

## Effect of mindfulness on fatigue, kinesiophobia and quality of life in patients with acute myocardial infarction

Mindfulness in myocardial infarction

Canan Demirci<sup>1</sup>, Metin Oksu<sup>2</sup>, Necla Ozer<sup>2</sup>, Leyla Ozdemir<sup>3</sup>

<sup>1</sup> Department of Nursing, Akdagmadeni School of Health, Yozgat Bozok University, Yozgat

<sup>2</sup> Department of Cardiology, Hacettepe University Adult Hospital, Ankara

<sup>3</sup> Department of Internal Medicine Nursing, Faculty of Nursing, Hacettepe University, Ankara, Turkey

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### Abstract

Aim: To investigate the effect of the brief mindfulness practice (MP) on fatigue, kinesiophobia, and quality of life (QoL) in patients with acute myocardial infarction (MI) was the purpose of the study.

Material and Methods: This study was designed as a randomized controlled study. The study was carried out with 56 MI patients. Participants were randomly assigned to the mindfulness group (MG) or a control group (CG). The MG patients received a 15 min MP session during eight weeks, comprising sitting and breathing for a total of eight weeks, while the CG patients received only a single-time attention-matched education.

Results: After completion of the MP, any significant difference was not found in the fatigue scores of the patients ( $p>0.05$ ). The kinesiophobia scores in the MG were significantly lower in the 4th, 8th and 12th weeks ( $p<0.05$ ). The QoL scores were significantly higher in the MG in the 8th week ( $p<0.05$ ).

Discussion: The MP practice can significantly improve the QoL, and this beneficial effect of MP is maintained particularly in the emotional aspect. Furthermore, the MP may decrease kinesiophobia in patients with MI. Based on the results of the study, MP may be recommended as mind-body-based complementary approaches within the scope of post-MI management.

### Keywords

Fatigue, Kinesiophobia, Mindfulness, Myocardial Infarction, Quality of Life

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Corresponding Author: Canan Demirci, Department of Nursing, Akdagmadeni School of Health, Yozgat Bozok University, Yozgat, Turkey.

E-mail: karadas.canan@gmail.com /canan.karadas@yobu.edu.tr P: +90 546 133 19 89

Corresponding Author ORCID ID: <https://orcid.org/0000-0002-3364-6276>

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## Introduction

Myocardial infarction (MI) is the most frequent manifestation of coronary artery disease (available at: <https://www.tkd.org.tr/TKDDData/Uploads/files/Turkiye-kalp-ve-damar-hastaliklari-onleme-ve-kontrol-programi.pdf>). In recent years, the survival rate after MI has increased due to the advances in MI treatment, including the widespread use of defibrillators in the coronary intensive care units (CICU), reperfusion algorithms, and additional treatments such as the coronary artery bypass graft [1]. However, patients continue to experience symptoms such as anxiety, depression, sleep disturbances, pain, and fatigue afterward [2,3]. Fatigue is experienced by nearly half of the patients after MI, and it lasts for about two months to a year during the post-treatment period [4,5]. Fatigue and other symptoms such as pain, palpitations, and dyspnea may cause difficulties in daily activities, which may decrease the functional independence of the patients due to stress, anxiety, and fear [4,6]. In the behavioral fear-avoidance model, the fear of movement situation is called "kinesiophobia" [7]. Kinesiophobia is an avoidance behavior and a natural and emotional adaptation reaction demonstrated after acute injuries. Perpetuating fear and avoidance behaviors after cardiac events may lead to negative physiological and psychological consequences [7]. Considering the symptom burden and reduced QoL after MI, supporting the patients through interventions is necessary. Psychosocial adaptation, lifestyle changes, cardiac rehabilitation interventions, and various complementary and integrative approaches have been applied for symptom management and increasing the QoL of the patients after MI [8,9]. Among complementary and integrative approaches, mindfulness-based approaches have drawn increasing attention in recent years for the treatment of various chronic diseases [10]. Mindfulness practice (MP), developed by Kabat-Zinn et al. (2013), is defined as a present-centered and purposive non-judgmental awareness. MP involves bringing an individual's attention to the experience of the present moment, including their thoughts, feelings, and physical sensations, with certain openness, curiosity, and acceptance [11]. The control of emotional response and the effective use of the breath reduce the tension in the body and increase the blood oxygen saturation in the patients. Therefore, MP may prove to be effective in reducing fatigue and kinesiophobia and improving the QoL in patients after MI. The present randomized controlled study aimed to investigate the effect of the MP on fatigue, kinesiophobia, and the QoL in patients with acute MI. The present study hypothesized that MP would (1) alleviate the fatigue severity, (2) decrease the kinesiophobia, and (3) improve the QoL in patients with acute MI.

## Material and Methods

### Trial design

The study was designed as a randomized controlled trial with two parallel groups and a 4-week follow-up period to investigate the effect of the MP on fatigue, kinesiophobia, and the QoL in patients with acute MI. The patients were divided into two groups: the mindfulness group (MG) and the control (CG) group.

### Inclusion and exclusion criteria

The inclusion criteria were as follows: (a) age between 18 and 75

years; (b) having received pharmacological reperfusion therapy after acute MI or the percutaneous coronary intervention (PCI); (c) no temporary or permanent pacemaker; (d) no diseases that would affect the breathing exercise; (e) no physical or mental health problems that could interfere with communication; (f) no diagnosis of cognitive, mental, or psychological illness; (g) no learning disabilities or difficulties; (h) ability to use a telephone; and (i) consent to participate in the study. The exclusion criteria were: (a) planned coronary artery bypass graft (CABG); (b) having experienced cardiogenic shock caused due to acute MI; (c) having hearing impairment; (d) living in a nursing home after discharge from the hospital; (e) currently not using any complementary therapy modalities known for stress-reducing.

### Participants and sample size

The study was conducted in November 2018-June 2020, in the CICU of a university hospital, Turkey. A total of 163 patients were contacted and 104 patients who did not fulfill the inclusion criteria were excluded. The remaining 59 patients were randomly divided into two study groups, following which three patients withdrew from the study due to discharge before receiving the MP education (n=1), refusal to share communication information (n=1), and withdrawal after the first interview (n=1). Therefore, the study was completed with a total of 56 patients with acute MI [MP (n=28) and CG (n=28)] (Figure 1).

As there were no similar studies available in the literature, it was not possible to calculate the required sample size in advance. Therefore, the power analysis was performed using the G-Power 3.0.10 program, based on the mean change in the MacNew Quality of Life Scale (MacNew) score between the 0th week and the 8th week (MG: from  $5.04 \pm 0.70$  to  $5.76 \pm 0.47$ ; CG: from  $5.17 \pm 0.85$  to  $5.37 \pm 0.51$ ). Accordingly, the power of the study was determined to be 89.8% with a significance level of 0.05 and an effect size of 0.79.

### Randomization, allocation, and blinding

The patients were evaluated for participation in the study within 24h of admission to the CICU, and the participants who met the inclusion criteria were selected. Stratified randomization was used to balance the age ( $\leq 50$  years and  $> 50$  years) and number of MI events (first-time MI and recurrent) between the study groups. After the stratification, the patients were assigned randomly into two groups (Group 1: 28; Group 2: 28) using "Random Number Generator" (1: Mindfulness group; 2: Control group) by the senior (4th) co-author who was not involved in the intervention procedures conducted afterward. All the training sessions were conducted by the principal investigator (PI), who was not blinded to the study groups.

### Recruitment

#### Study Procedure

The MP is, originally, a part of the mindfulness-based stress-reduction program [11]. Mindfulness interventions usually include yoga, walking meditation, guided imagery, body scans, and sitting meditation. In the present study, the research team included only mindful breathing and sitting meditation in the MP intervention.

The intervention procedures were performed at the CICU by the PI, who is certified and experienced in MP interventions. Each patient received the MP training individually on the day

of discharge, with face-to-face sessions conducted while they were in their beds with a dim light. Bed curtains were drawn prior to the sessions to ensure patient privacy and reduce distracting stimuli. The patients in the MP group were first provided with a description of mindfulness and its effects on the body. These theoretical sessions lasted for 15 min. After the completion of the theoretical sessions on MP, all the MP steps were practiced by the patients under the supervision of the PI for 15 min. The PI asked the participants to sit in a comfortable position on a chair with their backs straight and eyes closed. Then, the PI requested the participants to breathe deeply and focus on their breathing and the present moment throughout the session. Therefore, each participant in the MP group received a total of 30 min of training, including theoretical as well as practical sessions on MP. The PI also recorded the MP instructions using a voice recorder, generating an audio file for practicing the MP sessions at their home. The MP groups continued to practice the MP session for 15 min each day, for a total of eight weeks, at home. Daily reminders (text messages or phone calls) were sent to participants to motivate them to practice the MP and to evaluate their compliance with the study protocol.

The patients in the CG received only a one-time attention-matched education on the structure and function of the heart, including the heart anatomy, heart functions, coronary arteries, and the diseases of the heart. The attention-matched education was provided face-to-face and lasted for 15 min.

#### Outcome Measures

**Patient Information Form:** This form was originally developed by the researchers based on previous literature. It contains 14 questions regarding the socio-demographic characteristics and the current and previous health status [3,5,8].

**Piper Fatigue Scale (PFS):** This scale was originally developed by Piper et al. and the latest revision contains four sub-dimensions and 27 items, with a 0–10 scale for each item [12]. The total fatigue score, calculated by averaging 22 items, ranges from 0 to 10. The Turkish validity and reliability study was performed by Can et al. (2004), who reported Cronbach's alpha coefficient of 0.94 [13]. In the present study, the Cronbach alpha value was 0.96.

**Tampa Scale for Kinesiophobia for Heart (TSK-H):** Tampa Scale for Kinesiophobia (TSK) was adapted for cardiac diseases and named the TSK-Heart scale by Bäck et al. [14]. TSK-H comprises 17 items that assess the subjective rating of kinesiophobia, and each item is rated on a four-point Likert scale with scoring options ranging from “strongly disagree” to “strongly agree”. Acar et al. performed the Turkish validity and reliability study of the TSK-H and reported Cronbach's alpha value of 0.75 [15]. The Turkish version ranges between 17 and 68, with high values indicating a higher level of kinesiophobia. In the present study, Cronbach's alpha value was 0.67.

**MacNew Quality of Life Questionnaire (MacNew):** The MacNew tool was developed to measure the QoL of the patients with heart disease and comprises 27 questions containing three subscales. The MacNew sub-dimensions include the emotional functioning sub-dimension (EFS) (14-items), the physical functioning sub-dimension (PFS) (13-items), and the social functioning sub-dimension (SFS) (14-items). The total score is calculated by averaging the scores of all the questions and sub-

dimensions and ranges between 1 to 7, with higher scores representing better QoL. The Turkish validity and reliability study was conducted by Daskapan et al., who reported Cronbach's alpha value of 0.80 and the internal content index of 0.60 [16]. In the present study, the Cronbach's alpha value was obtained as 0.83.

#### Data Collection

The baseline data were collected during the first interview with the participants using the patient information form, PFS, TKS-H, and MacNew. The patients in both groups were re-assessed (follow-up assessment) in the 4th, 8th, and 12th weeks using the PFS, TKS-H, and MacNew.

#### Ethics statement

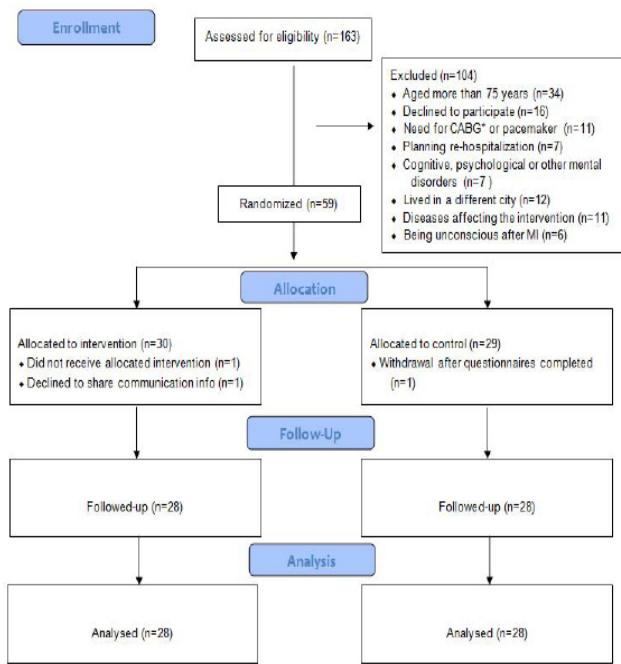
The study was approved by the clinical trials ethics committee [(Date: 2018-10-17, Decision number: 2018/18-29 (KA-180075)]. The authors of the present study thoroughly explained the study to all the participants, who were also asked to sign written informed consent.

#### Statistical analysis

Data were analyzed using the IBM SPSS version 23.0 (IBM Corp., Armonk, NY, USA). Data analysis was performed independently by a statistician from the research group. Comparisons of the MacNew, PFS, and TSK-H scores between the study groups were performed using Student's t-test. The statistical significance threshold for the two-tailed test and the analyzes was set at  $p<0.05$ .

#### Results

The mean age of all participants was  $55.0\pm10.0$  years. Among the patients, 67.9% of patients in the MG were 50 years and older and 78.6% experienced MI for the first time, while 67.9% of the patients in the CG were 50 years and older and 85.7% experienced MI for the first time. The majority of the participants in both groups were male (82.1% in MG; 85.7 in CG) and married (96.4%).



**Figure 1.** CONSORT flow diagram of the study sample

Both groups were similar in terms of age and previous MI history ( $p>0.05$ ). The analysis of the clinical characteristics revealed that 57.1% of the patients had at least one co-morbid disease in both study groups. ST-segment elevated MI type was observed at a 53.6% rate in MG and 67.9% in CG. Almost all the patients (92.9%) had a stent implanted (Table 1). Although not presented in any table, antiplatelet agents were the most prescribed agents in both groups (89.3% in the MG and 78.6% in the CG).

Study groups were homogeneous in terms of fatigue scores at baseline assessment ( $t:1.004$ ,  $p=0.32$ ). The mean total PFS scores of the participants in the MM group were 2.08 at the

**Table 1.** Socio-demographic characteristics and health status of the participants (N=56).

	MG (n=28)		CG (n=28)	
	n	%	n	%
Age (Mean±SD)	55.0±10.0		55.5±9.6	
≤50	9	32.1	9	32.1
>50	19	67.9	19	67.9
	t=0.000		p=1.000	
Number of MI				
First time	22	78.6	24	85.7
Repeated	6	21.4	4	14.3
	t=0.688		p=0.485	
Gender				
Male	23	82.1	24	85.7
Female	5	17.1	4	14.3
Educational level				
Primary and lower	12	42.9	12	42.9
Secondary and higher	16	57.1	16	57.1
Chronic condition existence				
Yes	16	57.1	16	57.1
No	12	42.9	12	42.9
Type of MI				
STEMI	15	53.6	19	67.9
NSTEMI	13	46.4	9	32.1
Stent implantation after MI				
Yes	26	92.9	28	100
No	2	7.1	-	-
Total	28	100	28	100

(Mean±SD): Mean±Standard Deviation; \*MI: Myocardial Infarction.

**Table 2.** Comparison of fatigue and kinesiophobia scores between the study groups (n=56).

Group	Baseline (Mean±SD)	4 <sup>th</sup> week (Mean±SD)	8 <sup>th</sup> week (Mean±SD)	12 <sup>th</sup> week (Mean±SD)
PFS	MG	2.08±1.87	0.90±0.99	0.47±0.78
	CG	1.56±2.01	1.12±1.59	0.98±1.52
	t	1.004	-0.621	-1.584
	p	0.32	0.54	0.12
TSK-H	MG	40.25±5.04	36.18±4.49	34.39±4.61
	CG	41.71±7.28	41.89±6.74	41.82±5.84
	t	-0.875	-3.734	-5.279
	p	0.39	0.001	0.000

(Mean±SD): Mean±Standard Deviation; PFS: Piper Fatigue Scores; TSK-H: Tampa Scale for Kinesiophobia-Heart t= Student T Test; p< 0.05

**Table 3.** Comparison of quality-of-life scores and sub-dimensions between the study groups (n=56).

Group	Baseline (Mean±SD)	4 <sup>th</sup> week (Mean±SD)	8 <sup>th</sup> week (Mean±SD)	12 <sup>th</sup> week (Mean±SD)
MacNew	MG	5.04±0.71	5.53±0.45	5.76±0.47
	CG	5.17±0.85	5.32±0.60	5.37±0.52
	t; p	-0.640; 0.53	1.436; 0.16	2.933; 0.005
EFS+	MG	4.75±0.61	5.16±0.49	5.44±0.48
	CG	4.80±0.70	4.99±0.63	5.15±0.54
	t; p	-0.293; 0.77	1.142; 0.26	3.257; 0.002
PFS+	MG	5.14±1.08	5.88±0.57	6.19±0.52
	CG	5.27±1.11	5.62±0.71	6.01±0.56
	t; p	-0.460; 0.65	1.507; 0.14	2.694; 0.01
SFS+	MG	5.46±0.9	5.40±0.50	5.66±0.49
	CG	5.47±0.98	5.10±0.61	5.19±0.62
	t; p	-0.013; 0.99	2.000; 0.06	3.130; 0.003

(Mean±SD): Mean±Standard Deviation; MacNew: MacNew Quality of life Scale; EFS: Emotional functioning sub-dimension; PFS: Physical functioning sub-dimension; SFS: Social functioning sub-dimension; t= Student T Test value; p< 0.05

baseline, 0.9 at week 4, 0.47 at week 8, and 0.44 at week 12 of the study. The corresponding scores for the CG were 1.56, 1.12, 0.98, and 0.76, respectively. These scores represented that the patients in both groups experienced mild fatigue after MI. When comparing the total PFS scores between the study groups, no significant difference was observed for the baseline assessment and all the assessments ( $p>0.05$ ) (Table 2).

Concerning the kinesiophobia scores, the TSK-H score was 40.25 for MG and 41.71 for CG at the baseline assessment. The study groups were homogeneous in terms of the kinesiophobia scores at the beginning of the study ( $t:-0.875$ ,  $p=0.39$ ). The TSK-H scores were 36.18 in the 4th week, 34.39 in the 8th week, and 34.96 in the 12th week in the MG, and the corresponding scores in the CG were 41.71, 41.89, 41.82, and 41.00, respectively. The TSK-H scores obtained for the MG were significantly lower than those obtained for the CG in the 4th week ( $t:-3.734$ ,  $p=0.001$ ), 8th week ( $t:-5.279$ ,  $p=0.000$ ), and 12th week ( $t:-4.390$ ,  $p=0.000$ ) (Table 2).

In terms of the QoL scores, the study groups were homogenous at the baseline assessment ( $t:-0.640$ ,  $p=0.53$ ). After the completion MP sessions, the QoL scores were significantly higher in the MG compared to the CG at 8th week ( $t:2.933$ ,  $p=0.005$ ). In the all sub-dimensions of MacNew presented significant differences in favor of MG at week 8 ( $t:3.257$ ,  $p=0.002$  for EFS;  $t:2.694$ ,  $p=0.01$  for PFS; and  $t:3.130$ ,  $p=0.003$  for SFS). Only the EFS sub-dimension continued to present significantly higher differences in the follow-up assessment at week 12 ( $t:2.118$ ,  $p=0.039$ ) (Table 3).

## Discussion

The current study was designed as a randomized controlled trial that investigated the effects of 8-week MP interventions on fatigue, kinesiophobia, and the QoL in patients with acute MI. Although the literature contains studies investigating the effects of MP in heart failure patients, to the best of our knowledge, no study investigating the effects of MP on acute MI patients has been conducted so far. Consistent with our hypothesis, MP decreased kinesiophobia and improved the QoL

in patients with MI. The other hypothesis, that "MP can reduce fatigue", was not confirmed by the results of the present study. Fatigue is considered an important determinant of the health status in acute MI patients [4,5]. However, studies investigating the association between MP and fatigue in patients with MI are limited. In several systematic reviews evaluating the effectiveness of MP in heart diseases, it was concluded that MP increases the functional capacity and effectively reduces fatigue [3,17]. However, contrary to the findings reported in the literature, the MP intervention did not prove to be effective in reducing fatigue in the present study. The literature emphasizes that fatigue is influenced by various factors, such as patient characteristics, repeated MI, MI severity, and the treatment applied (PCI, CABG, or implanting cardiac battery) for MI [2,4,5]. Since our study sample comprised mostly middle-aged and male patients, with no diseases and a high QoL before the MI, and the participants also reported a mild fatigue level at the beginning of the study, the authors presumed patient characteristics as the possible reason for the ineffectiveness of the MP intervention in fatigue.

The importance of encouraging patients to perform physical activity during the early period after MI is well-recognized as secondary prevention [7,18]. However, kinesiophobia presents a striking barrier to the implementation of cardiac rehabilitation, including body movements or exercises. Several studies have reported that heart disease patients largely experience kinesiophobia [7,19]. Throughout the study, the kinesiophobia scores remained significantly lower in the MG. In the present study, the mean kinesiophobia scores were significantly decreased in the MG, with this positive effect lasting for four weeks after the completion of the MP intervention. Therefore, it is proposed that MP can reduce kinesiophobia and could, therefore, be applied as a complementary intervention in cardiac rehabilitation programs.

The American Heart Association published a scientific statement based on a systematic review of the studies on meditation, suggesting a possible benefit for the CAD patients [20]. In support of our third hypothesis, the MP intervention in the present study improved the QoL and all its sub-dimensions in the intervention group compared to the control group. The positive effect of MP on the emotional dimension was maintained in the follow-up assessment, while the achievements in the physical and social dimensions could not be sustained after the intervention was terminated. Recent studies have also reported significant improvements in the QoL and its sub-dimensions immediately after the mindfulness intervention and after three or six months in MI and other cardiac patients [21]. Gotink et al. (2017) reported that a 12-week online MP intervention improved the patients' QoL in the intervention group [22]. Nijjar et al. (2019) reported improvements, even though statistically insignificant, in the health-related QOL at three months in the intervention group compared to the controls [23]. The MP may increase selective and sustainable attention and awareness, thereby reducing the negative processes and consequently, the emotional vulnerability, contributing to improving the QoL. In other words, the efficacy of MP in the QoL might be based on the patient's self-realization of automatic thoughts.

## Limitation

Despite the encouraging findings, the present study also had certain limitations. One of the limitations is the difficulty in masking the patients' groups due to the nature of the intervention presented as a barrier to a double-blind, randomized control trial. The PI collected the data for both groups and also administered all the interventions. Lastly, the generalizability of the study findings to all MI patient populations is low as our sample consists mostly of young and male patients.

## Conclusion

In conclusion, the present study demonstrated that the MP intervention can significantly improve the QoL in patients with MI, and this effect is maintained, particularly in the emotional aspect. Moreover, the MP is effective in decreasing kinesiophobia, and this beneficial effect was sustained for one month after the intervention was terminated. On the contrary, the MP intervention could not affect the fatigue scores. On the basis of these findings, it is recommended to integrate the MP intervention into clinical practice as an integrative and complementary intervention within the scope of secondary prevention after acute MI. The study procedure should be replicated in different study samples, including the patients with low ejection fraction and those requiring CABG or pacemaker following acute MI.

## Scientific Responsibility Statement

*The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.*

## Animal and human rights statement

*All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.*

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## Conflict of interest

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